

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
FLAMMER, et al.)Examiner:
)Marina Lamm
Serial No.: 10/067,596)
)Group Art Unit:1616
Filed: February 5, 2002)
)Confirmation No:5911
For: "ANTI-DANDRUFF AND ANTI-ITCH)
COMPOSITIONS CONTAINING SENSATE AND)
SENSATE ENHANCER-CONTAINING)
COMPOUNDS")

Commissioner of Patents
Mail Stop Amendment P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RICHARD BODEN UNDER 37 CFR §1.132

Richard Boden, being duly sworn, deposes and says:

1. He is currently employed by INTERNATIONAL FLAVORS & FRAGRANCES Inc., the assignee of the above-identified patent application as Research Fellow in the Ingredient Research and Development Department of International Flavors & Fragrances Research and Development located at Union Beach, New Jersey, and he has held that position for a period since May 1, 2004. Prior to holding that position, from June 1999, he held the position of Technical Perfume Manager Department of International Flavors & Fragrances Inc. Research and Development.

2. He holds the Ph.D. Degree in Organic Synthesis which he received in 1979 from University of Rochester.

3. He is a co-inventor on the above-identified Patent Application, Serial Number 10/643,542 filed on August 19, 2003.

4. He is familiar with the U.S. Patent Office Action of July 17, 2006 drafted in connection with the prosecution of the above-identified patent application Serial Number 1010/643,542 filed on August 19, 2003 wherein previously-presented claims 1-4, 6, 7, 12-16 and 20 of the above-identified patent application were rejected under 35 USC §103(a) as being unpatentable over the disclosure of Nakatsu et al. published European Patent Application 1,121,927 A2 taken further together with any of the secondary references, Beilharz et al. U.S. Patent 5,494,675, Rapaport, U.S. Patent 5,730,965 or Micheal Published U.S. Patent Application US 2001/0043912.

5. He is fully familiar with the subject matter disclosed and claimed in the above-identified patent application, Serial Number 10/643,542 filed on August 19, 2003 and he is fully familiar with the newly-presented claims thereof set forth as follows and contained in the amendment accompanying this affidavit, being filed in the United States Patent and Trademark Office:

27. (new) An anti-dandruff composition comprising:

- (a) an anti-dandruff agent;**
- (b) a cooling sensate material which comprises a C₁-C₃ alkyl or dialkyl-N-substituted menthane carboxamide; and**
- (c) a cooling sensate enhancer material which is a C₇-C₁₂ alkanolic acid vanillamide**

wherein the weight ratio of anti-dandruff agent :cooling sensate material :cooling sensate enhancer material is from about 0.7 up to about 1.5 antidandruff agent:from about 0.5 up to about 1.5 cooling sensate material:from about 0.001 up to about 0.1 cooling sensate enhancer material.

28. (new) The anti-dandruff composition of claim 27 wherein the anti-dandruff agent is the zinc salt of 1-hydroxy-2-pyridinethione; the cooling sensate material is a mixture of menthol and 2-isopropyl-N,2,3-trimethyl butyramide; and the cooling sensate enhancer is n-nonylic acid vanillamide.

29. (new) The anti-dandruff composition of claim 27 wherein the cooling sensate material is N-ethyl-p-menthane-3-carboxamide.

30. (new) An anti-dandruff shampoo comprising water, a shampoo base and from about 0.5% up to about 2.5% by weight of the shampoo of the anti-dandruff composition of claim 27.

31. (new) An anti-dandruff shampoo comprising water, a shampoo base and from about 0.5% up to about 2.5% by weight of the shampoo of the anti-dandruff composition of claim 28.

32. (new) An anti-dandruff shampoo comprising water, a shampoo base and from about 0.5% up to about 2.5% by weight of the shampoo of the anti-dandruff composition of claim 29.

33. (new) The anti-dandruff shampoo of claim 30 additionally comprising a fragrance, each of the components of which has a $C \log_{10}P$ (i) in the range of from about 1 up to about 3, without restriction on the molecular weight of each of said components, (ii) in the range of from about greater than 3 up to about 10 for components, each of which has a molecular weight in the range of from about 120 up to about 350 or (iii) in the range of from about 1 up to about 3 without restriction on the molecular weight range of each of said components and in the range of from about greater than 3 up to about 10 for components each of which has a molecular weight in the range of from about 120 up to about 350, wherein P is the n-octanol/water partition coefficient of the fragrance component, the concentration range of said fragrance being in the range of from about 0.03% up to about 5.0% by weight of the anti-dandruff shampoo.

34. (new) The anti-dandruff shampoo of claim 31 additionally comprising a fragrance, each of the components of which has a $C \log_{10}P$ (i) in the range of from about 1 up to about 3, without restriction on the molecular weight of each of said components, (ii) in the range of from about greater than 3 up to about 10 for components, each of which has a molecular weight in the range of from about 120 up to about 350 or (iii) in the range of from about 1 up to about 3 without restriction on the molecular weight range of each of said components and in the range of from about greater than 3 up to about 10 for components each of which

has a molecular weight in the range of from about 120 up to about 350, wherein P is the n-octanol/water partition coefficient of the fragrance component, the concentration range of said fragrance being in the range of from about 0.03% up to about 5.0% by weight of the anti-dandruff shampoo.

35. (new) A method for reducing *pruritis* of the mammalian scalp caused by *seborrheic dermatitis* comprising the steps of (i) applying to said mammalian scalp a *pruritis* reducing quantity and concentration of the shampoo of claim 30 for a *pruritis* reducing period of time and (ii) applying to said mammalian scalp a rinsing quantity of water in order to remove residual shampoo.

36. (new) The method of claim 35 wherein application of the shampoo to the mammalian scalp also exerts at least one of:

- i. a substantial soothing effect;
- ii. a deep-cleansed effect as measured by the IFF squeak test;
- iii. a significant itch reduction;
- iv. a substantial tingling effect;
- v. a substantial warming effect;
- vi. a substantial cooling effect; or
- vii. a significantly enhanced "menthol/medicinal" aroma.

He has supervised the carrying out of the following examples which compare the prior art with the invention as defined according to the claims 27-36 as set forth in ¶8, *supra*:

EXAMPLE AA

PREPARATION OF FRAGRANCE FOR USE IN SHAMPOO OF EXAMPLE BA

The following fragrance is prepared for use with the shampoo of Example BA

Ingredients	Parts by Weight
α -irone	7.0
myristicin	4.0
2-methoxynaphthalene	3.0
benzaldehyde	2.0
β -phenylethyl alcohol	12.0
nerol	7.0
eugenol	8.0
isoeugenol	8.0
amyl salicylate	4.0
β -caryophyllene	14.0
cedryl acetate	10.0
cyclohexyl salicylate	4.0
γ -dodecalactone	3.0
geranyl anthranilate	3.0

EXAMPLE BA

PREPARATION OF FRAGRANCE-CONTAINING SHAMPOO BASE FOR USE IN CONJUNCTION WITH EXAMPLES IA-VA INCLUSIVE

At the rate of 0.8%, the fragrance prepared according to Example AA is admixed with the following shampoo base:

Component	Parts by Weight
ammonium lauryl sulfate (27% aqueous solution)	56.0
citric acid	0.50
sodium citrate	0.50
coconut monoethanolamide	5.0
propylene glycol distearate	3.0
methyl paraben	0.50
propyl paraben	0.50
color solution	0.20
water	33.8

EXAMPLE IA

To the shampoo of Example BA, zinc pyrithione at the rate of 1%, menthol at the rate of 0.5%, N,2,3-trimethyl-2-isopropyl-butyramide at the rate of 0.25% and nonyl acid vanillamide at the rate of 0.002% are added. The effects exerted during use and post-use of the shampoo are set forth in the tables of the results, *infra*.

EXAMPLE IIA

To the shampoo Example BA, zinc pyrithione at the rate of 1% and menthol at the rate of 0.5% are added. The effects exerted during use and post-use of the shampoo are set forth in the tables of the results, *infra*.

EXAMPLE IIIA

To the shampoo of Example BA, zinc pyrithione at the rate of 1%, menthol at the rate of 0.5% and N,2,3-trimethyl-2-isopropyl-butyramide at the rate of 0.35% are added. The effects exerted during use and post-use of the shampoo are set forth in the tables of the results, *infra*.

EXAMPLE IVA

To the shampoo of Example BA, zinc pyrithione at the rate of 1% is added. The effects exerted during use and post-use of the shampoo are set forth in the tables of the results, *infra*.

EXAMPLE VA

To the shampoo of Example BA, zinc pyrithione at the rate of 1% and N,2,3-trimethyl-2-isopropyl-butyramide at the rate of 0.35% are added. The effects exerted during use and post-use of the shampoo are set forth in the tables of the results, *infra*.

TABLES OF RESULTS

In the following tables I, II and III, the effects for which values, determined using a 17 member panel; and as defined on pages 10, 11 and 12 of the above identified application, including the 'soothing effect', V_S and the 'deep cleansing effect', V_{DC} are set forth as follows:

- i. a substantial soothing effect
- ii. a deep-cleansed effect
- iii. a significant itch reduction
- iv. a substantial tingling effect
- v. a substantial warming effect
- vi. a substantial cooling effect
- vii. a significantly enhanced "menthol/medicinal" effect

TABLE I OF RESULTS

Example	Value of Effect(i) (V _S)(soothing)		Value of Effect(ii) (V _{DC})(deep cleansing)		Value of Effect (iii) (itch reduction)		
	on use	5 min. post use	on use	5 min. post use	on use	5 min. post use	15 min. post use
IA (per claim 31)	10	10	7	6	9.4	9.4	*
IIA (shampoo BA with Menthol +zinc pyrithione)	6	5	8	8	10	10	*
IIIA(as IA but without nonyl acid vanillamide)	10	10	7	7	10	9.4	*
IVA(shampoo BA with zinc pyrithione)	*	*	*	*	8.5	8.5	6.5
VA(shampoo BA with zinc pyrithione and N,2,3-trimethyl-2-isopropyl butyramide)	*	*	*	*	9	8.5	7.5
BA(shampoo BA alone)	3	3	3	3	9.4	9.4	*

Note *: Result not measured

TABLE II OF RESULTS

Example	Value of Effect(iv) (tingling)			Value of Effect(v) (warming)			Value of Effect (vi) (cooling)		
	on use	5 min. post use	15 min. post use	on use	5 min. post use	15 min. post use	on use	5 min. post use	15 min. post use
IA (per claim 31)	4.7	4.7	*	3.4	1.8	*	2.2	2.1	*
IIA (shampoo BA with Menthol +zinc pyrithione)	6.5	5.3	*	3.8	1.7	*	3.2	2.6	*
IIIA(as IA but without nonyl acid vanillamide)	5.3	5.9	*	3.5	1.8	*	2.9	2.3	*
IVA(shampoo BA with zinc pyrithione)	4.5	2	2	2.2	1.4	1.6	3.0	3.0	2.4
VA(shampoo BA with zinc pyrithione and N,2,3-trimethyl-2-isopropyl butyramide)	4	3.5	2	2.2	0.6	1.0	2.4	3.8	2.4
BA(shampoo BA alone)	0.6	0.6	*	2.9	2.5	*	1.2	0.6	*

Note *: Result not measured

TABLE III OF RESULTS

Example	Value of Effect(vii) (menthol/medicated)		Arithmetic Average of Effects (i) –(vii), inclusive		
	on use	5 min. post use	on use	5 min. post use	15 min. post use
IA (per claim 31)	8	8	6.38	6.24	*
IIA (shampoo BA with Menthol +zinc pyrithione)	8	8	6.50	6.18	*
IIIA(as IA but without nonyl acid vanillamide)	10	10	6.95	6.96	*
IVA(shampoo BA with zinc pyrithione)	*	*	4.55	3.9	3.13
VA(shampoo BA with zinc pyrithione and N,2,3-trimethyl- 2-isopropyl butyramide)	*	*	4.4	4.2	3.22
BA(shampoo BA alone)	1	1	3.01	3.01	*

Note *:Result not measured.

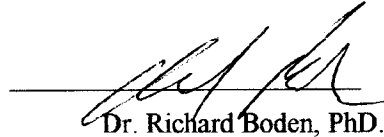
10. As a result of her review of the results of the experiments and results thereof as described in ¶9, supra, show has drawn the following conclusions:

- (a) With respect to the arithmetic average of effects (i) – (vii) in **TABLE III OF RESULTS**, in ¶9, supra, inclusion of the combination of the anti-dandruff agent, zinc pyrithione with the cooling sensate, 2-isopropyl-N,2,3-trimethyl butyramide and the cooling sensate enhancer, nonyl acid vanillamide both on use and 5 minutes post use enables the anti-dandruff shampoo to have significantly unexpected, advantageous and unobvious properties.
- (b) With respect to the soothing (i) effect as set forth in the **TABLE I OF RESULTS** supra, the combination of the anti-dandruff agent, zinc pyrithione, with the cooling sensate, 2-isopropyl-N,2,3-trimethyl butyramide and the cooling sensate enhancer, nonyl acid vanillamide, both on use and 5 minutes post use enables the shampoo to have significantly unexpected, advantageous and unobvious properties.

11. It is his further conclusion, as a result of his conclusions as set forth in ¶10, supra, that the employment of the compositions and processes defined by claims 24 – 33 as set forth in ¶8, supra, give rise to significantly unobvious, advantageous and unexpected results when compared with the teachings of Nakatsu et al. taken in view of either Beilharz et al., Rapaport or Michael.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Nov 11, 2006
Date


Dr. Richard Boden, PhD.